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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,034

09/15/2006

Keiko Shimamoto

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EXAMINER

BARKER, MICHAEL P

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

11/24/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,034	<b>Applicant(s)</b> SHIMAMOTO ET AL.	
	<b>Examiner</b> MICHAEL BARKER	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/15/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-14 are pending and rejected.

### **Response to Restriction/Election**

Applicant's arguments per the Restriction Requirement put forth 03/05/2009 are persuasive. The Restriction Requirement is hereby withdrawn, and all claims are rejoined.

### **Rejections**

#### **35 USC 103(a)**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected as obvious over WO/2003/000698 A1, published 01/03/2003.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

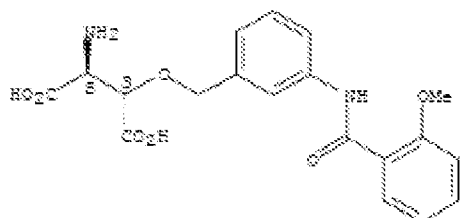
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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The '698 publication discloses numerous beta-benzyloxyaspartate derivatives with an amino group on the benzene ring. With the exception of the radioactive labeling on the benzoyl group, the following compounds fall within the genus recited in claim 1:

RN 480428-54-2 CASLUS  
CN L-Aspartic acid, 3-([3-([3-methoxybenzoyl]amino[phenyl]methoxy]-, (3S)-  
(CA INDEX NAME)

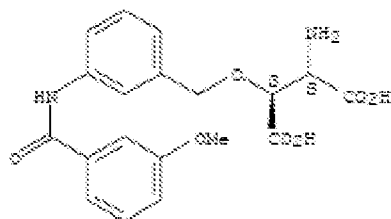
Absolute stereochemistry.



1)

RN 480438-55-4 CASLUS  
CN L-Aspartic acid, 3-([3-([3-methoxybenzoyl]amino[phenyl]methoxy]-, (3S)-  
(CA INDEX NAME)

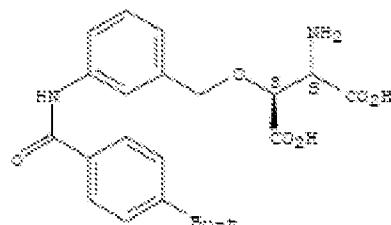
Absolute stereochemistry.



2)

RN 479693-57-8 CASLUS  
CN L-Aspartic acid, 3-([3-([4-(1,1-dimethylethyl)benzoyl]amino[phenyl]methoxy]-, (3S)- (CA INDEX NAME)

Absolute stereochemistry.



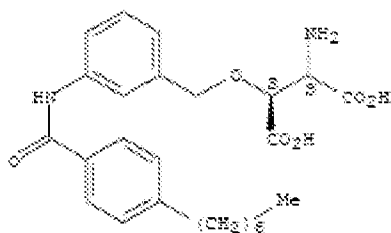
3)

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RN 475433-65-3 CAPLUS

CN L-Aspartic acid, 3-[[3-[(4-heptylbenzoyl)amino]phenyl]methoxy]-, (3S)-  
(CA INDEX NAME)

Absolute stereochemistry.

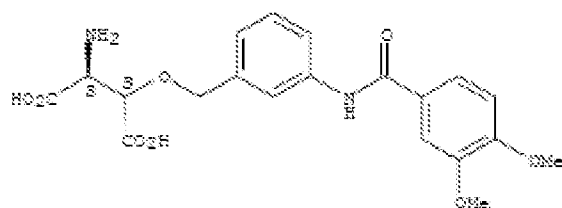


4)

RN 480433-67-4 CAPLUS

CN L-Aspartic acid, 3-[[3-[(3,4-dimethoxybenzoyl)amino]phenyl]methoxy]-, (3S)-  
(CA INDEX NAME)

Absolute stereochemistry.

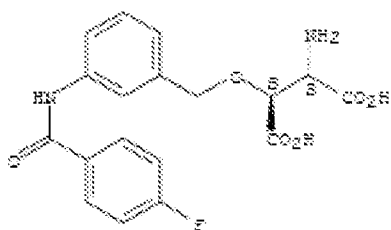


5)

RN 480433-71-2 CAPLUS

CN L-Aspartic acid, 3-[[3-[(4-fluorobenzoyl)amino]phenyl]methoxy]-, (3S)-  
(CA INDEX NAME)

Absolute stereochemistry.

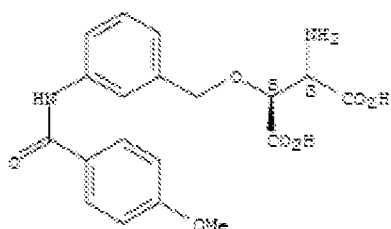


6)

RN 480433-66-5 CAPLUS

CN L-Aspartic acid, 3-[[3-[(4-methoxybenzoyl)amino]phenyl]methoxy]-, (3S)-  
(CA INDEX NAME)

Absolute stereochemistry.

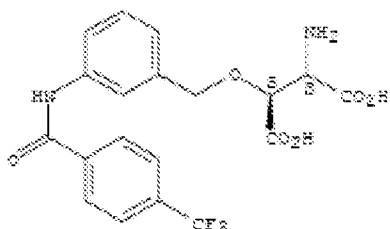


7)

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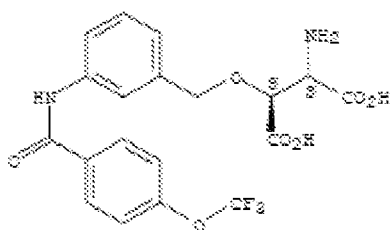
RN 480439-73-4 CAPLUS  
 CN L-Aspartic acid,  
 3-[[[2-[[4-(trifluoromethyl)benzoyl]amino]phenyl]methoxy]-  
 , (3S)- (CA INDEX NAME)

Absolute stereochemistry.



8)

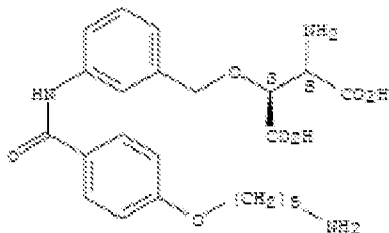
RN 480439-72-3 CAPLUS  
 CN L-Aspartic acid,  
 3-[[[2-[[4-(trifluoromethoxy)benzoyl]amino]phenyl]methoxy]-



9)

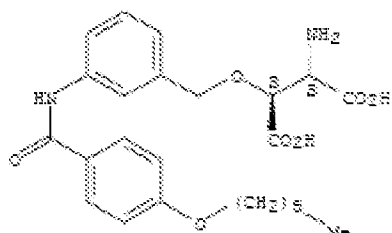
RN 480439-75-7 CAPLUS  
 CN L-Aspartic acid, 3-[[[2-[[4-[[5-  
 aminopentyl]oxy]benzoyl]amino]phenyl]methoxy]-, (3S)- (CA INDEX NAME)

Absolute stereochemistry.



10)

BN 450492-74-5 CASLUS  
CN L-Aspartic acid, 2-[[[2-[[4-(hexyloxy)benzoyl]amino]phenyl]methoxy]-,  
(3S)-  
(CA INDEX NAME)  
Absolute stereochemistry.



11)

Each of the compounds listed above differs from Applicant's compounds recited in claim 1 in that none are depicted as radiolabeled at the equivalent X position.

However, as p. 13 of the '698 publication notes,

Some compounds of formula (1) are useful for radio-isotope labeled ligands for identification of transporter proteins. Isotope labeled ligands may be obtained by well known synthetic procedures, using the hydroxybenzoyl intermediates for R group in the formula (1) with the reaction, for example, of labeled methyl iodide to yield the desired labeled ligand as shown in Scheme 2. Some of the radio-isotope labeled methyl iodides are commercially available, including, deuterium-labeled methyl iodide, tritium-labeled methyl iodide, Carbon 14-labeled or Carbon 11-labeled methyl iodides.

Accordingly, the '698 publication teaches compounds which meet the limitations of generic claim 1 and further suggests that certain of these compounds are suitable for radiolabeling, thereby rendering claims 1, 2, 7, 8, and 10 obvious. Additionally, the '698 publication teaches that the radiolabeled ligands are useful for identification of transporter proteins which, as demonstrated throughout the publication, include

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glutamate transporter proteins. Accordingly, the '698 publication renders claim 9 obvious.

Furthermore, the process of preparing said compounds is depicted in the '698 publication at Schemes 1 and 2, pp. 9 and 14, respectively, and mirrors Applicant's claims 5, 6, 13, and 14. In addition, Schemes 1 and 2 also render obvious Applicant's precursor compounds recited in claims 3, 4, 11, and 12.

### **Obviousness Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 7, 10, 12, 14, and 15 of U.S. Patent No. 7,247,652. Although the conflicting claims are not identical, they are not patentably



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distinct from each other because the aforementioned claims encompass Applicant's current claims. The only difference between the compounds according to claims 6 and 7 and the claimed compounds is an H at the equivalent R2 and R1 positions of the claimed compounds rather than a lower aliphatic alkyl group (includes methyl) as currently claimed. It has long been held that substitution of methyl for hydrogen is obvious in cases where the compounds would be expected to confer similar properties. In this case, both the compounds of the '652 patent and current claims are related to glutamate uptake inhibition. Thus, the substitution of H for methyl would be obvious, since the substitution does not effect the ability of the claimed compounds in glutamate uptake inhibition.

**Conclusion**

Any inquiry concerning this Office Action should be directed to Michael P. Barker at (571)272-0303, normally reachable from Monday through Friday, 8 am to 5 pm. If attempts to reach the Examiner are unsuccessful, please try the Examiner's supervisor, Joseph K. McKane at (571)272-0699.

Information regarding the status of an application may be obtained from the private or public PAIR system. Information about PAIR may be found at <http://pair-direct.uspto.gov> or 866.217.9197.

/MICHAEL BARKER/

Examiner, Art Unit 1626

/Kamal A Saeed/

Primary Examiner, Art Unit 1626